



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/617,208 | 07/10/2003 | Alexander N. Glazer | B00-016-2 | 3116 |
| 23379 | 7590 | 05/16/2006 | EXAMINER | |
| RICHARD ARON OSMAN SCIENCE AND TECHNOLOGY LAW GROUP 242 AVE VISTA DEL OCEANO SAN CLEMEMTE, CA 92672 | | | KAM, CHIH MIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|-----------------|---------------|
| | 10/617,208 | GLAZER ET AL. |
| Examiner | Art Unit | |
| Chih-Min Kam | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 March 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4, 6, 8-13 and 19-22 is/are rejected.

7) Claim(s) 5, 7 and 14-18 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/10/03; 9/8/03.
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-20, in the response filed March 11, 2006 is acknowledged. Applicants has requested rejoinder of corresponding method claims 21-22. Upon reconsideration, the restriction requirement is withdrawn. Therefore, claims 1-22 are examined. A declaration of Drs. Alexander Glazer and Yuping Cai, and Exhibit IV filed September 8, 2003 are acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12, 13 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 12 and 13 are indefinite because of the use of the term "substantially transparent". The term cited renders the claim indefinite, it is not clear to what extent the displayed domain is transparent to wavelengths of visible light absorbed by phycobiliproteins, or, to what extent the displayed domain is transparent to wavelengths of energy emitted by the phycobiliproteins.
4. Claims 20-22 are indefinite as to how a functional oligomeric phycobiliprotein is produced since the claim only recites the step of expressing the fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain in the cell, it is not clear how to produce the functional oligomeric phycobiliprotein from the fusion protein. Claims 21-

22 are included in the rejection for being dependent of a rejected claim and not correcting the deficiency of the claim from which they depend.

5. Claim 22 is indefinite because of the use of the term “improved functional folding”. The term cited renders the claim indefinite, it is not clear what the term “functional folding” means, and it is also not clear how the method can provide improved functional folding of the displayed domain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 8-13, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Colleen Mary Toole (Dissertation; UMI microfilm 9839498, available on December 14, 1998 according to Proquest; a formal document will be forward to applicant upon receiving).

Toole teaches the construction and expression of the CpcB strep-tag protein incorporated in a phycobilisome assembly in *E.coli* (Chapter III, pages 151-167), where the phycobilisomes from ST13 lysates are purified using a streptavidin column eluted with a buffer (pages 54-55; page 161; claims 1, 2 and 4), and where a small peptide sequence SAWRHPQRGG, a biotin mimic that binds to streptavidin, was added to the carboxyl terminal of the CpcB subunit with a peptide linker (Fig. 27; claim 6) and used as an affinity tag for the purification of biliprotein subunits on the streptavidin columns. A construct encoding phycocyanin β subunit fused to the strep-tag was prepared and introduced into cyanobacterial transformation vector creating

pCBST13 (see Fig. 25; page 152), and expression and assembly of CpcB-St was carried out in strain 4R (page 155), where phycobilisomes isolated from ST13 contain CpcA and CpcBst (Fig. 26; claims 3, 8-11, 19 and 20). The reference also indicates the whole-cell absorbance spectra for R20 (positive control), 4R (negative control, PC-minus) and ST13 cultures showed that the PC content in ST13 (as measured by the signal near 625 nm) was clearly increased relative to that in 4R but was less than the PC level of R20, and energy transfer from PC to AP in ST13 was similar to R20 cells with prominent emission in the 685 nm region and minimal fluorescence near 638 nm (page 155, claims 12-13).

In the Declarations of Drs. Alexander Glazer and Yuping Cai, paragraphs 2 and 3 state Exhibit IV is photocopies of 15 pages from a laboratory notebook of Yuping Cai describing their work performed between November 1997 and April 1998 in the United States, which demonstrates the production of a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain incorporated in a functional oligomeric phycobiliprotein; a cell comprising a functional oligomeric phycobiliprotein comprising a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain; and a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain incorporated in a functional oligomeric phycobiliprotein, wherein the oligomeric phycobiliprotein provides a fluorescent tag.

The Declarations of Drs. Alexander Glazer and Yuping Cai and Exhibit IV filed September 8, 2003 have been considered and have established the claimed invention prior to the published date (i.e., January 1999) of the abstract of the dissertation by Colleen Mary Toole, thus the abstract is not used as prior art. However, the claimed invention is not established against the

dissertation by Colleen Mary Toole because the dissertation is available on December 14, 1998, which is more than one year before the filing date of parent application (December 21, 1999).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 20-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-18 of U. S. Patent 6,649,376. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20-21 in the instant application disclose a method of making a functional oligomeric phycobiliprotein, comprising incubating a cell comprising a nucleic acid encoding a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain to express the fusion protein and produce a functional oligomeric phycobiliprotein; and a method for making a functional displayed domain, comprising incubating the cell to express the fusion protein and produce the oligomeric phycobiliprotein, cleaving a peptide bond between the functional displayed domain and the functional phycobiliprotein domain, and separating the functional displayed domain from the functional phycobiliprotein domain. This is obvious variation in view of claims 11-18 of the patent which disclose a method of making the fusion

protein by expressing a nucleic acid encoding a polypeptide comprising a functional displayed domain and a functional phycobiliprotein domain in a cell or cell-free expression system, and combining the polypeptide with a phycobiliprotein subunit under conditions to form the fusion protein; and a method for isolating a functional displayed domain by making the fusion protein, cleaving a peptide bond between the functional displayed domain and the functional phycobiliprotein domain, and separating the functional displayed domain from the functional phycobiliprotein domain. Both sets of claims are directed to a method of making a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain incorporated in a functional oligomeric phycobiliprotein by expressing the fusion protein in a cell or cell-free expression system; and a method for making a functional displayed domain by making the fusion protein, cleaving a peptide bond between the functional displayed domain and the functional phycobiliprotein domain, and separating the functional displayed domain from the functional phycobiliprotein domain. Therefore, claims 20-21 in instant application and claims 11-18 of the patent are obvious variations of a method of making a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain incorporated in a functional oligomeric phycobiliprotein by expressing the fusion protein in a cell or cell-free expression system; and a method for making a functional displayed domain by making the fusion protein, cleaving a peptide bond between the functional displayed domain and the functional phycobiliprotein domain, and separating the functional displayed domain from the functional phycobiliprotein domain.

Claim Objections

8. Claims 5, 7 and 14-18 are objected to because the claim is dependent from a rejected claim.

Conclusion

9. Claims 1-4, 6, 8-13 and 19-22 are rejected; and claims 5, 7 and 14-18 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK
May 12, 2006